DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 9 1998

.Anthony J. Roccograndi
Sonnenreich & Roccograndi P.C.
2600 Virginia Avenue, Suite 300
Washington, DC 20037

Re: Docket No. 98P-0456

Dear Mr. Roccograndi:

This responds to your letter, dated June 23, 1998, on behalf of Weck Closure Systems, L.C., of Research Triangle Park, North Carolina, in which you request an exemption from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables for the Weck cardiac pacing wires. The pacing wires include a breakaway Keith needle intended to pierce the chest wall. The pacing wire is used during and shortly after open chest surgery to provide a means to pace the heart in the event of surgical complications that require temporary pacing. The Food and Drug Administration (FDA) is granting your petition as requested.

The Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) (62 Fed. Reg. 25497; May 9, 1997) is intended to eliminate the risk of patient electrocution, by requiring electrode lead wires used with medical devices to be protected against inadvertent contact with electrical power sources or contact with electrical ground. The performance standard (21 CFR 898.14) provides for affected parties to request an exemption or variance from the performance standard, through submission of a citizen petition in accordance with 21 CFR 10.30.

Temporary pacing electrodes (pacing wires) have been classified in 21 CFR 870.3680(a) and are required to comply with the performance standard after May 9, 2000. However, for the pacing wires described in your petition, compliance with the performance standard would interfere with the intended use of the pacing wire, thereby posing a greater risk to health than that posed by a failure to comply with the performance standard. Accordingly, your request is granted and Weck cardiac pacing wires are exempted from compliance with the performance standard. This exemption is limited to those temporary pacing wires that include breakaway needles used to pierce the chest wall. Please note that FDA recently granted a similar petition, exempting all "heart wires" that include a breakaway myocardial needle.

98P-0456

PAV 1

I trust this response addresses your concerns. If additional information is needed, please contact Stewart Crumpler in our Office of Compliance, at (301) 594-4659.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health